SODIUM CHLORIDE 0.9% FREEFLEX

PRODUCT INFORMATION

Name of the medicine
Sodium chloride
NaCl
CAS registry number: 7647-14-5

Description
Sterile isotonic solution of sodium chloride 9g/L in Water for Injections, containing no preservatives (normal saline).

Pharmacology
Sodium Chloride Injection 0.9% provides a source of sodium ions (154 mmol/L), chloride ions (154 mmol/L) and water.

Indications
Normal saline can be used as the vehicle for many parenteral drugs and as an electrolyte replenisher for maintenance or replacement of deficits of extracellular fluid.

It can also be used as a sterile irrigation medium.

Contraindications
Sodium Chloride 0.9% is contraindicated in patients with congestive heart failure, severe renal impairment, conditions of sodium retention, oedema, liver cirrhosis and irrigation during electrosurgical procedures.

Precautions
Do not use unless the solution is clear. The entire contents of the bag should be used promptly.

When used as a vehicle for intravenous drug delivery, the product information document of such drugs should be checked prior to use to ensure compatibility with the sodium chloride solution. Reconstitution instructions should be read carefully.

Excessive administration of sodium chloride causes hypernatraemia, resulting in dehydration of internal organs, hypokalaemia and acidosis. Monitoring of fluid, electrolyte and acid/base balance may be necessary. Congestive heart failure and pulmonary oedema may be precipitated, particularly in patients with cardiovascular disease or those receiving corticosteroids, corticotrophin or other drugs that may give rise to sodium retention. Sodium chloride should be administered with care to patients with congestive heart failure, hypertension, peripheral or pulmonary oedema, hypoproteinaemia, impaired renal function, urinary tract obstruction, pre-eclampsia and very young or elderly patients. Intravenous infusion during or immediately after surgery may result in sodium retention.

Given that there is a possibility of systemic absorption of irrigation solutions, the same precautions apply.

Use in Pregnancy
Safety in pregnancy has not been established. Use is recommended only when clearly indicated.

Use in Lactation
Safety in lactation has not yet been established. Use of this product while breastfeeding is recommended only when potential benefits outweigh potential risks to the newborn infant.

Paediatric Use
In paediatric use, the dose should be calculated for each patient based on clinical condition, including body weight and laboratory data.

Use in Elderly
For use in elderly, the dose should be based on individual patient assessment, including weight, fluid and electrolyte status and renal and cardiac function.

Interactions
Additives may be incompatible with sodium chloride.
Co-medication of drugs inducing sodium retention may exacerbate any systemic effects.

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Adverse Reactions

Excessive amounts of sodium chloride may cause hypernatraemia, hypokalaemia and acidosis. Proper use of normal saline as a vehicle for parenteral drugs or as an electrolyte replacement therapy is unlikely to result in adverse effects.

Hypernatraemia rarely occurs with therapeutic doses of sodium chloride, but may occur in excessive administration. A serious complication of this is dehydration of the brain causing somnolence and confusion, which may progress to convulsions, coma and ultimately respiratory failure and death. Pulmonary embolism or pneumonia may also result. Other symptoms include thirst, reduced salivation and lacrimation, fever, tachycardia, hypertension, headache, dizziness, restlessness, weakness and irritability.

Infusion of excess sodium chloride 0.9% solution may cause fluid overload or electrolyte imbalance. Intravenous administration of solutions may cause local reactions including pain, vein irritation and thrombophlebitis. Extravasation of solution may cause tissue injury.

If any adverse effects are observed during administration, discontinue infusion, evaluate the patient and institute appropriate supportive treatment.

Displaced catheters or drainage tubes can lead to irrigation or infiltration of unintended structures or cavities. Excessive volume or pressure during irrigation of closed cavities may result in distension or disruption of tissues. Inadvertent contamination from careless technique may transmit infection. Adverse effects resulting from irrigation of body cavities, tissues or indwelling catheters and tubes are usually avoidable when appropriate procedures are followed.

Dosage and Administration

The dosage of sodium chloride as a vehicle for parenteral drugs and as an electrolyte replenisher must be calculated after consideration of clinical and laboratory data.

For use in one patient, on one occasion only. It does not contain antimicrobials. Any unused portion should be discarded. Care should be taken with intravenous technique to avoid injection site reactions and infections.

Overdosage

Infusion of excess intravenous fluid may cause hypervolaemia and electrolyte imbalances. Excess sodium chloride in the body produces general gastrointestinal effects of nausea, vomiting, diarrhoea and cramps. Salivation and lacrimation are reduced, while thirst and sweating are increased. Hypotension, tachycardia, renal failure, peripheral and pulmonary oedema and respiratory arrest may occur. CNS symptoms include headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. If any adverse effects are observed during administration, discontinue infusion, evaluate the patient and institute appropriate supportive treatment.

Treatment

Normal plasma sodium concentrations should be carefully restored at a rate not greater than 10-15 mmol/day using I.V. hypotonic saline. Dialysis may be necessary if there is significant renal impairment, the patient is moribund or plasma sodium levels are greater than 200 mmol/L. Convulsions may require diazepam or other appropriate treatment.

Presentation and storage conditions

Freeflex bags - Store below 25°C.

50mL	AUST R 144596
100mL	AUST R 144609
250mL	AUST R 144632
500mL	AUST R 29745
1000mL	AUST R 47400

Poison schedule of the medicine

Australia: Nil
New Zealand: General Sales Medicine

Name and address of the sponsor

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